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Attorneys for Defendants Par Pharmaceutical Companies, Inc. and
Par Pharmaceutical, Inc. and Counterclaim Plaintiff Par Pharmaceutical, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SHIRE LLC, Plaintiff, v. PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC., Defendants.	C.A. No. 1:15-cv-1454-RMB-JS

DEFENDANTS PAR PHARMACEUTICAL COMPANIES, INC. AND PAR PHARMACEUTICAL, INC.'S ANSWER, SEPARATE DEFENSES, AND PAR PHARMACEUTICAL, INC.'S COUNTERCLAIMS

Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (together, "Par"), by and through their attorneys, for their Answer to the Complaint of Plaintiff Shire LLC ("Shire" or "Plaintiff"), hereby declare as follows:

NATURE OF THE ACTION

1. Paragraph 1 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq*. Par avers that Par Pharmaceutical, Inc. submitted Abbreviated New Drug Application ("ANDA") No. 206159 to the United States Food and Drug Administration (the "FDA"). Par further avers that Par Pharmaceutical, Inc. seeks FDA approval of its ANDA prior to the expiration of United States Patent No. RE42,096 (the "'096 patent") and U.S. Patent No. RE41,148 (the "'148 patent"). Par denies that Shire is entitled to any relief.

PARTIES

2. Par is without knowledge and information sufficient to form a belief as to the state of incorporation and principal place of business Shire LLC. Par thus denies the allegations of Paragraph 2.

3. Par admits that Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

4. Par admits that Par Pharmaceutical, Inc. is registered to do business in the State of New Jersey under Business I.D. No. 0100071541. Par further admits that Par Pharmaceutical, Inc. is a registered manufacturer and wholesaler of drugs with the New Jersey Department of Health under Registration No. 5004032.

5. Paragraph 5 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that Par Pharmaceutical conducts business in the State of New Jersey.

6. Par admits that Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of Delaware. Par avers that Par Pharmaceutical Companies, Inc. has a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977. Par denies the remaining allegations of Paragraph 6.

7. Par admits that Par Pharmaceutical Companies, Inc. is registered to do business in the State of New Jersey under Business I.D. No. 0100946477.

8. Par admits that Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is required, Par admits the allegations of Paragraph 9.

10. Paragraph 10 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 10.

11. Par denies the allegations of Paragraph 11.

12. Paragraph 12 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest personal jurisdiction or venue in this judicial district. Par denies the remaining allegations of Paragraph 12.

JURISDICTION AND VENUE

13. Paragraph 13 states a legal conclusion to which no response is required. To the extent a response is required, Par admits that the Complaint purports to be a civil action arising

under the patent laws of the United States, and alleges patent infringement of the '096 patent and the '148 patent. Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest jurisdiction or venue in this judicial district. Par denies that it engaged or is engaging in any act that violates the patent laws of the United States, or engaged in or is engaging in any act resulting in liability for patent infringement. In addition, Par denies that subject matter jurisdiction exists based on any acts by Par Pharmaceutical Companies, Inc. and therefore denies that Par Pharmaceutical Companies, Inc. is a proper party in this case. Par further denies that venue is proper for Par Pharmaceutical Companies, Inc. Par denies the remaining allegations of Paragraph 13.

14. Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 14.

15. Paragraph 15 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 15.

16. Paragraph 16 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 16.

17. Paragraph 17 states a legal conclusion to which no response is required. To the extent a response is required, Par states, for the limited purposes of this action only, that Par Pharmaceutical, Inc. does not contest personal jurisdiction in this judicial district. Par denies the remaining allegations of Paragraph 17.

SHIRE'S PATENTS AND APPROVED ADDERALL XR® DRUG PRODUCT[1]

18. Par is without knowledge and information sufficient to admit or deny the allegations of Paragraph 18 and thus denies the same.

19. Par admits that the prescribing information for Adderall XR® dated July 24, 2014 states that Adderall XR® may be used once daily, and that it contains dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate. Par avers that according to FDA, Adderall XR® is currently approved in six dosage strengths: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 19 and thus denies the same.

20. Par admits that the '096 patent, on its face, is titled "Oral Pulsed Dose Drug Delivery System," and states that it is a reissue of U.S. Patent No. 6,322,819, which issued on November 27, 2001. Par further admits that the '096 patent is, on its face, assigned to Shire. Par further admits that what appears to be a copy of the '096 patent is attached to the Complaint as Exhibit A. Par denies the remaining allegations of Paragraph 20.

21. Par admits that the '148 patent, on its face, is titled "Oral Pulsed Dose Drug Delivery System," and states that it is a reissue of U.S. Patent No. 6,605,300, which issued on August 12, 2003. Par further admits that what appears to be a copy of the '148 patent is attached to the Complaint as Exhibit B. Par avers that the '148 patent is, on its face, assigned to Shire Laboratories, Inc. Par is without knowledge and information sufficient as to admit or deny whether Shire owns the '148 patent. Par denies the remaining allegations of Paragraph 21.

[1] Headings are reprinted here with the same language as used in Shire's Complaint simply for ease of reference, and do not constitute an admission by Par.

22. Par admits that FDA approved the marketing of Adderall XR® under New Drug Application ("NDA") No. 21-303. Par further admits that the '096 and '148 patents are listed in FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") with reference to NDA No. 21-303. Par denies that FDA listed the '096 and '148 patents in the Orange Book because one or more of the claims of each of those patents cover Adderall XR®. Par is without knowledge and information sufficient to admit or deny the remaining allegations of Paragraph 22 and thus denies the same.

DEFENDANTS' ANDA AND NOTICE OF PARAGRAPH IV CERTIFICATION

23. Par avers that Par Pharmaceutical, Inc. submitted ANDA No. 206159 to FDA pursuant to 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, or sale of the product described in this ANDA ("Par's ANDA Product") prior to the expiration of the '096 and '148 patents. Par denies the remaining allegations of Paragraph 23.

24. Par avers that Par Pharmaceutical, Inc.'s counsel sent Shire a notice letter dated January 14, 2015, providing a written notification of Par Pharmaceutical, Inc.'s ANDA and its accompanying certification. Par avers that its notice letter advised Shire that pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), ANDA No. 206159 contained a certification stating that the claims of the '096 patent and the '148 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's ANDA Product. Par denies the remaining allegations of Paragraph 24.

25. Paragraph 25 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 25.

26. Par avers that if FDA approves Par Pharmaceutical, Inc.'s ANDA, Par Pharmaceutical, Inc. may manufacture, offer for sale, or sell Par's ANDA Product within the

United States or import Par's ANDA Product into the United States. Par denies the remaining allegations of Paragraph 26.

27. Paragraph 27 states a legal conclusion to which no response is required. To the extent a response is required, Par denies the allegations of Paragraph 27.

28. Paragraph 28 states a legal conclusion to which no response is required. To the extent a response is required, Par avers that Shire filed its Complaint against Par within 45 days of the date of Par Pharmaceutical, Inc.'s notice letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '096 PATENT

29. No response is required to the general reallegation and incorporation by reference of the allegations set forth in Paragraphs 1 through 28 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through 28.

30. Par avers that Par Pharmaceutical, Inc. submitted to FDA, and is currently seeking FDA approval for, ANDA No. 206159. Par denies the remaining allegations of Paragraph 30.

31. Par denies the allegations of Paragraph 31.

32. Par denies the allegations of Paragraph 32.

33. Par denies the allegations of Paragraph 33.

34. Par admits that Par Pharmaceutical, Inc. was aware of the '096 prior to submitting ANDA No. 206159 to FDA. Par denies the remaining allegations of Paragraph 34.

35. Par denies the allegations of Paragraph 35.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '148 PATENT

36. No response is required to the general reallegation and incorporation by reference of the allegations set forth in Paragraphs 1 through 35 of the Complaint. To the extent a response is required, Par hereby incorporates by reference its responses to Paragraphs 1 through

35.

37. Par avers that Par Pharmaceutical, Inc. submitted to FDA, and is currently seeking FDA approval for, ANDA No. 206159. Par denies the remaining allegations of Paragraph 37.

38. Par denies the allegations of Paragraph 38.

39. Par denies the allegations of Paragraph 39.

40. Par denies the allegations of Paragraph 40.

41. Par admits that Par Pharmaceutical, Inc. was aware of the '148 prior to submitting ANDA No. 206159 to FDA. Par denies the remaining allegations of Paragraph 41.

42. Par denies the allegations of Paragraph 42.

ANSWER TO SHIRE'S REQUEST FOR RELIEF

Par denies that Shire is entitled to the relief they seek in Paragraphs (a) through (g) or any relief at all for the allegations made in the Complaint.

SEPARATE DEFENSES

Par pleads the following defenses in response to Shire's allegations, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Par reserves the right to allege additional defenses in the event that discovery or other analysis indicates that additional affirmative or other defenses are appropriate.

FIRST SEPARATE DEFENSE

43. Each purported claim for relief in the Complaint is barred for failure to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

44. The claims of the '096 and '148 patents are invalid for failing to meet one or more requirements for patentability under Title 35 of the United States Code.

THIRD SEPARATE DEFENSE

45. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par 's ANDA Product do not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '096 and '148 patents.

46. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product do not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '096 and '148 patents under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE

47. Par's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Par reserves the right to assert additional defenses in the event that discovery or other analysis indicates that additional affirmative defenses are appropriate.

COUNTERCLAIMS

Counterclaimant Par Pharmaceutical, Inc. asserts the following Counterclaims against Shire LLC ("Shire") and Counterclaim-Defendants Shire US Inc. ("Shire US") and Shire Development LLC ("Shire Development") that United States Patent Nos. RE42,096 (the "'096 patent") and RE41,148 (the "'148 patent") are not infringed by the product described in

Abbreviated New Drug Application ("ANDA") No. 206159, and/or are invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*

THE PARTIES

1. Defendant/Counterclaimant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of Delaware with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. On information and belief, and based on Shire's allegations, Counterclaim-Defendant/Plaintiff Shire LLC is a limited liability company organized and existing under the laws of the State of Kentucky with a principal place of business at 9200 Brookfield Ct., Suite 108, Florence, Kentucky 41042.

3. On information and belief, Counterclaim-Defendant Shire US Inc. is a corporation organized and existing under the laws of the State of New Jersey with a principal place of business at 725 Chesterbrook Blvd., Wayne, Pennsylvania 19087.

4. On information and belief, Counterclaim-Defendant Shire Development LLC is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 725 Chesterbrook Blvd., Wayne, Pennsylvania 19087.

NATURE OF THE ACTION

5. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Par Pharmaceutical, Inc. seeks declarations that the '096, '148, '819, and '300 patents are not infringed by the product described in Par Pharmaceutical Inc.'s ANDA No. 206159, invalid for violation of one or more provisions of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq.*, and/or surrendered pursuant to 37 C.F.R. § 1.178.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq*. This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

7. This Court has personal jurisdiction over Shire based on, *inter alia*, Shire's filing of this lawsuit in this jurisdiction. This Court has personal jurisdiction over Shire US and Shire Development, because, upon information and belief, they conduct substantial business in, and have regular and systematic contact with, this judicial district.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

9. The '096 patent, on its face, is titled "Oral Pulsed Dose Drug Delivery System," and states its date of reissue as February 1, 2011.

10. The '096 patent is a reissue of U.S. Patent No. 6,322,819, which was surrendered upon the issuance of the '096 patent. *See* 37 C.F.R. § 1.178.

11. On information and belief, and based on Shire's allegations, Shire currently owns the '096 patent.

12. The '148 patent, on its face, is titled "Oral Pulsed Dose Drug Delivery System," and states its date of reissue as February 23, 2010.

13. The '148 patent is a reissue of U.S. Patent No. 6,605,300, which was surrendered

upon the issuance of the '148 patent. *See* 37 C.F.R. § 1.178.

14. On information and belief, and based on Shire's allegations, Shire currently owns the '148 patent.

15. On information and belief, and based on Shire's allegations, Shire Development is the holder of New Drug Application ("NDA") No. 21-303 for capsules containing dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate in six dosage strengths: 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg, sold in the United States as Adderall XR®.

16. On information and belief, FDA approved NDA No. 21-303 on October 11, 2001.

17. On information and belief, Shire US manufactures and markets the Adderall XR® capsules.

18. The '096 and '148 patents are listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") listing of the United States Food and Drug Administration ("FDA") with respect to NDA No. 21-303.

19. On information and belief, one or both of Shire US and Shire Development hold licenses to the '096 and '148 patents.

20. Par Pharmaceutical, Inc. submitted ANDA No. 206159 to FDA, requesting approval to engage in the commercial manufacture, use, importation, sale, and/or offer for sale in the United States of capsules containing dextroamphetamine sulfate, dextroamphetamine saccharate, amphetamine aspartate monohydrate, and amphetamine sulfate in 5 mg, 10 mg, 15 mg, 20 mg, 25 mg, and 30 mg dosage strengths before the stated expiration date of the '096 and '148 patents. Par Pharmaceutical, Inc. made a certification pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) (a "Paragraph IV Certification") that no valid or enforceable claim of the

'096 and '148 patents would be infringed by the commercial manufacture, use, importation, sale, and/or offer for sale of the products that are the subject of ANDA No. 206159 ("Par's ANDA Product").

21. On February 26, 2015, Shire filed its Complaint alleging infringement by Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. of the '096 and '148 patents.

FIRST COUNT
(Declaration of Invalidity of the '096 Patent)

22. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 21 as if fully set forth herein.

23. The claims of the '096 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

24. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Shire and Counterclaim-Defendants concerning the validity of the '096 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

25. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '096 patent is invalid.

SECOND COUNT
(Declaration of Noninfringement of the '096 Patent)

26. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 25 as if fully set forth herein.

27. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '096 patent.

28. The manufacture, use, sale, offer for sale, and/or importation into the United States of the Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '096 patent under the doctrine of equivalents.

29. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Shire and Counterclaim-Defendants concerning the alleged infringement of the '096 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

30. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '096 patent is not infringed.

THIRD COUNT
(Declaration of Invalidity of the '148 Patent)

31. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 30 as if fully set forth herein.

32. The claims of the '148 patent are invalid for failing to meet one or more requirements for patentability of Title 35 of the United States Code, including 35 U.S.C. § 101 *et seq*.

33. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Shire and Counterclaim-Defendants concerning the validity of the '148 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

34. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '148 patent is invalid.

FOURTH COUNT
(Declaration of Noninfringement of the '148 Patent)

35. Par Pharmaceutical, Inc. incorporates by reference Paragraphs 1 through 34 as if fully set forth herein.

36. The manufacture, use, sale, offer for sale, and/or importation into the United States of Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '148 patent.

37. The manufacture, use, sale, offer for sale, and/or importation into the United States of the Par's ANDA Product does not and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '148 patent under the doctrine of equivalents.

38. A definite and concrete, real and substantial, justiciable controversy exists between Par Pharmaceutical, Inc. and Shire and Counterclaim-Defendants concerning the alleged infringement of the '148 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

39. Par Pharmaceutical, Inc. is entitled to a judicial declaration that the '148 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par Pharmaceutical, Inc. requests the following relief:

a) Dismissing Shire's Complaint with prejudice and denying each request for relief made by Shire;

b) Declaring all claims of the '096 patent invalid;

c) Declaring all claims of the '096 patent not infringed by the manufacturing, use, sale, offer for sale, or importation into the United States of Par's ANDA Product;

d) Declaring all claims of the '148 patent invalid;

e) Declaring all claims of the '148 patent not infringed by the manufacturing, use, sale, offer for sale, or importation into the United States of Par's ANDA Product;

f) Declaring that Par Pharmaceutical, Inc. has a lawful right to obtain FDA approval for the product as described in ANDA No. 206159 and that Par Pharmaceutical, Inc. has a lawful right to manufacture, import, use, sell, and/or offer to sell the product as described in ANDA No. 206159;

g) Holding that the 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii) be shortened to expire immediately;

h) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Par Pharmaceutical, Inc. its attorneys' fees, costs, and expenses in this action; and

i) Awarding Par Pharmaceutical, Inc. such other and further relief as the Court deems just and proper.

Dated: March 19, 2015

Respectfully submitted

SAIBER LLC
Attorneys for Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. and Counterclaim Plaintiff Par Pharmaceutical, Inc.

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Par hereby certifies that this matter is related to matters pending before this Court captioned *Shire LLC v. Amerigen Pharm. Ltd.*, Civ. A. No. 1:14-cv-06095 (RMB-JS) and *Shire LLC v. CorePharma, LLC*, Case No. 1:14-cv-05694 (RMB-JS). The undersigned counsel for Par further certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: March 19, 2015

s/ Sean R. Kelly
Sean R. Kelly

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Par hereby certifies that Par seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: March 19, 2015

s/ Sean R. Kelly
Sean R. Kelly